EUROPEAN
COMMISSION

Brussels, 2.9.2022
C(2022) 6479 (final)

COMMISSION IMPLEMENTING DECISION

of 2.9.2022

amending the conditional marketing authorisation granted by Decision C(2020) 9284(final) for "Tecartus - brexucabtagene autoleucel", an orphan medicinal product for human use

(Text with EEA relevance)

(ONLY THE DUTCH TEXT IS AUTHENTIC)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[1],

Having regard to Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products[2],

Having regard to Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products[3], and in particular Article 17(2) thereof,

Having regard to the changes to the terms of the decision granting the marketing authorisation requested by Kite Pharma EU B.V. in accordance with Regulation (EC) No 1234/2008,

Having regard to the opinions of the European Medicines Agency, formulated on 21 July 2022 by the Committee for Medicinal Products for Human Use and on 25 July 2022 by the Committee for Orphan Medicinal Products,

Whereas:

(1) Commission Decision C(2020)7318(final), adopted in accordance with Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products designated "Autologous peripheral blood T cells CD4 and CD 8 selected and CD 3 and CD 28 activated transduced with retroviral vector expressing anti- CD 19 CD 28/ CD 3-zeta chimeric antigen receptor and cultured" as an orphan medicinal product.

[1] OJ L 136, 30.4.2004, p. 1.
[2] OJ L 18, 22.1.2000, p. 1.
[3] OJ L 334, 12.12.2008, p. 7.

(2) The European Medicines Agency's opinion is favourable to the variation of the terms of the decision granting the marketing authorisation as submitted by the marketing authorisation holder.

(3) The review of the data submitted by Kite Pharma EU B.V. on 19 June 2022 has shown that the new therapeutic indication proposed for the medicinal product "Tecartus - brexucabtagene autoleucel" brings significant clinical benefit in comparison with existing therapies. Therefore, an additional year of marketing protection in accordance with Article 14(11) of Regulation (EC) No 726/2004 should be granted.

(4) Decision C(2020) 9284(final) should therefore be amended accordingly. The Union Register of Medicinal Products should also be updated.

(5) For the sake of clarity and transparency, it is appropriate, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C(2020) 9284(final) should therefore be replaced.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2020) 9284(final) is amended as follows:

1) Annex I is replaced by the text set out in Annex I to this Decision;

2) Annex II is replaced by the text set out in Annex II to this Decision;

3) Annex III is replaced by the text set out in Annex III to this Decision.

Article 2

Based on the conclusions set out in Annex IV to this Decision, the additional year of marketing protection is granted in accordance with Article 14(11) of Regulation (EC) No 726/2004.

Article 3

This Decision is addressed to Kite Pharma EU B.V., Tufsteen 1, 2132 NT Hoofddorp, Nederland.

Done at Brussels, 2.9.2022

For the Commission

Sandra GALLINA
Director-General